

BOX AF

Dkt. 1919/40441-CY/JPW/JML

Response under 37 C.F.R. §1.116  
Expedited Procedure  
Group Art Unit: 1806

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Walter P. Carney and Sara J. McKenzie  
Serial No. : 08/488,180 Examiner : T. Scheiner  
Filed : June 7, 1995 Group Art Unit : 1806  
For : DETECTION, QUANTIFICATION OF NEU RELATED PROTEINS  
IN THE BIOLOGICAL FLUIDS OF HUMANS

1185 Avenue of the Americas  
New York, New York 10036  
April 29, 1998

Assistant Commissioner for Patents  
Washington, D.C. 20231

BOX: AF

Sir:

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GROUP 1800

COMMUNICATION IN RESPONSE TO JANUARY 7, 1998 FINAL  
OFFICE ACTION UNDER 37 C.F.R. §1.116 AND PETITION FOR  
A ONE-MONTH EXTENSION OF TIME

This Communication is submitted in response to January 7, 1998 Final Office Action which was issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the January 7, 1998 Final Office Action was originally due April 7, 1998. Applicants hereby request a one-month extension of time. The fee for a one-month extension of time is ONE HUNDRED AND TEN DOLLARS (\$110.00) and a check including this amount is enclosed herewith. Thus, a response to the January 7, 1998 Final Office Action is now due May 7, 1998. Accordingly, this Communication is timely filed.

On page 2 of the January 7, 1998 Final Office Action, the Examiner stated that claims 19-24 have been entered by the amendment filed October 6, 1997, and that claims 13-24 are pending in the

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**Rejections Withdrawn**

The Examiner withdrew the rejection of claims 16-18 under 35 U.S.C. §112, first paragraph, in view of applicants' assurances of the deposit of biological material.

The Examiner withdrew the rejection of claims 16-18 under 35 U.S.C. §102(a) as anticipated by McKenzie et al. (Oncogene, Vol. 4, No. 5, pp. 543-548, May 1989) in view of the explicit disclosure of antibodies TA1, OD3, and NB3 in parent Application Serial No. 07/182,501 (filed April 18, 1988).

The Examiner withdrew the rejection of claims 13 and 15 under 35 U.S.C. §102(b) as anticipated by Drebin et al. (Nature, Vol. 312, No. 5994, pp. 545-548, December 1984) in view of the Declaration of Arthur M. Bruskin, filed October 20, 1997 Under 37 C.F.R. §1.132.

The Examiner withdrew the rejection of claim 14 under 35 U.S.C. §103 as unpatentable over Drebin et al. in view of the Declaration of Arthur M. Bruskin, filed October 20, 1997, Under 37 C.F.R. §1.132.

The Examiner withdrew the rejection of claims 16-18 under 35 U.S.C. §103 as unpatentable over Masuko et al. (Jpn. J. Cancer Res., Vol. 80, pp. 10-14, January 1989) in view of the explicit disclosure of antibodies TA1, OD3, and NB3 in parent Application Serial No. 07/182,501 (filed April 18, 1988).

**Rejection Under 35 U.S.C. §102(a) - McKenzie et al.**

The Examiner maintained the rejection of claims 13 and 15 under 35 U.S.C. §102(a) as being anticipated by McKenzie et al. for reasons of record.

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The Examiner stated that applicants urge that the subject matter of these claims is supported in parent Application Serial No. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3, and NB3. However, the Examiner stated, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human neu gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The Examiner alleged that the recognition of a class of antibodies binding the extracellular domain is not evident in parent Application Serial No. 07/182,501. The Examiner requested that applicant note that parent Application Serial No. 07/182,501 has been unavailable to the Examiner for review for some time; and that if applicants can provide official photocopies of any language from the parent application supporting the general recognition of a class of antibodies binding the extracellular domain, it would be appreciated, and this and the following rejections would be obviated:

In response, applicants respectfully traverse the rejection of claims 13 and 15 under 35 U.S.C. §102(a) as being anticipated by McKenzie et al. Applicants maintain that recognition of a class of antibodies binding the extracellular domain of neu is indeed disclosed in parent Application Serial No. 07/182,501. For the Examiners convenience, applicants attach hereto as Exhibit A a copy of Application Serial No. 07/182,501. Applicants maintain that this copy is a true copy of the application as originally filed, however, it is not an "official" photocopy as requested by the Examiner.

U.S. Application No. 07/182,501 discloses antibodies to neu specific for the extracellular domain. Specifically, the application recites "[p]referred antibodies are specific for the extracellular domain of the neu encoded gene product." See page

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15, first paragraph. On page 48, third paragraph, the application also recites "[u]sing the full length protein presented by viable cells as the immunogen, it is possible to generate a collection of monoclonal antibodies with specificities that span the entire length of the extracytoplasmic domain of the protein." Furthermore, the application discloses antibodies as specific for the extracellular domain in other locations, for example, see page 14, last sentence to page 15; page 16, lines 13-16, and page 48, line 12 to page 49, line 4.

Applicants acknowledge that the Examiner stated that all standing rejections would be obviated if applicants indicated language from the parent application supporting the general recognition of a class of antibodies binding the extracellular domain.

Thus, applicants maintain that the rejection of claims 13 and 15 under 35 U.S.C. §102(a) as being anticipated by McKenzie et al. (1989) is not proper since the filing date of parent application Serial No. 07/182,501 is April 18, 1988. As to the following three rejections based upon either Masuko et al. (1989) or McKenzie et al. (1989), applicants maintain that such rejections are also not proper in view of the April 18, 1988 filing date of U.S. Serial No. 07/182,501.

In view of the above, applicants respectfully request that the Examiner reconsider and withdraw this rejection and withdraw the three rejections recited hereinbelow. Applicants earnestly solicit the allowance of pending claims 13-24.

**Rejection Under 35 U.S.C. §102(a) - Masuko et al.**

The Examiner maintained the rejection of claims 13 and 15 under 35 U.S.C. §102(a) as being anticipate by Masuko et al. for reasons of

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record.

The Examiner stated that applicants urge that the subject matter of these claims is supported in parent Application Serial No. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3. However, the Examiner stated, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human neu gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The Examiner further stated that the recognition of a class of antibodies binding the extracellular domain is not evident in parent Application Serial No. 07/182,501.

In response, applicants traverse the rejection of claims 13 and 15 under 35 U.S.C. §102(a) as being anticipate by Masuko et al. Applicants direct the Examiner to the discussion hereinabove.

**Rejection Under 35 U.S.C. §103(a) - McKenzie et al.**

The Examiner maintained the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over McKenzie et al. for reasons of record.

The Examiner stated that applicants urge that the subject matter of these claims is supported in parent Application Serial No. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3, however, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human neu gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The Examiner stated that the recognition of a class of antibodies binding the extracellular domain is not evident in parent Application Serial No. 07/182,501.

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In response, applicants respectfully traverse the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over McKenzie et al. Applicants direct the Examiner to the discussion hereinabove.

Rejection Under 35 U.S.C. §103(a) - Masuko et al.

The Examiner maintained the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over Masuko et al. for reasons of record.

The Examiner stated that applicants urge that the subject matter of these claims is supported in parent Application Serial No. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3, however, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human neu gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The Examiner stated that the recognition of a class of antibodies binding the extracellular domain is not evident in parent Application Serial No. 07/182,501.

In response, applicants respectfully traverse the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over Masuko et al. Applicants direct the Examiner to the discussion hereinabove.

Claims 16-24 allowable

The Examiner stated that claims 16-24 are allowable.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

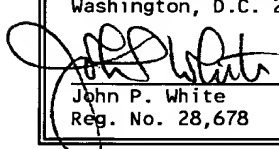
No fee, other than the \$110.00 extension of time fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents,  
Washington, D.C. 20231.



John P. White  
Reg. No. 28,678

4/29/98  
Date